

REMARKS

Regarding the Amendments to the Claims

Claims 1 and 21 have been amended to clarify that the composition of the invention, appearing in the claimed device and kit, comprises at least the elements of an absorbent matrix, a humectant, a pH-stabilizing agent and an adsorbent material.

New claim 22 is supported in the specification on page 6, lines 25 to 27.

New claim 23 is supported by the inherent disclosure of the specification, claim 19 and Example 1.

Response to rejection of claims 14 and 16-18 under 35 U.S.C. § 102(b)

The Examiner rejects claims 14 and 16-18 for anticipation by U.S. Patent No. 4,081,402 to Levy et al. ("Levy"). Levy is cited as allegedly teaching the combination of an absorbent matrix, a humectant, a pH-stabilized agent and an absorbent material.

As understood by Applicant, Levy describes the use of hydrogel matrix discs ("FASTABs"), which contain components such as glycerol and activated carbon. As shown in Figure 2 of Levy, the FASTABs (18) can be added to test samples in test tubes to selectively absorb antigens (12 or 14) and to exclude antibody-bound antigens (12 or 14 bound to 16). In Example 2, "blank" and "correction" tubes are prepared as controls, containing buffer instead of sample. Apparently, when a FASTAB is added to the correction tube, containing buffer, the result is a combined "composition" that allegedly contains an absorbent matrix, a humectant, a pH-stabilized agent and an absorbent material.

Applicant traverses as follows. As used in the claims, the "absorbent matrix" "can take up or absorb liquid" (specification on page 4, lines 7-8). By themselves, the FASTABs described in Levy apparently do not contain buffer as prepared (see Levy, column 12, table in Example 1), and therefore do not meet the limitations of claim 14. Rather, the cited composition of Levy is the combination of the FASTAB *absorbing* the buffer in the test tube. The FASTABs can be used dehydrated, fully hydrated or partially hydrated (Levy, column 4, lines 59-61). However, in each case, the FASTAB discs fail to meet limitations in claim 14.

If the FASTAB is used in dehydrated form, when the dehydrated disc is added the buffer in the "correction" tube, the disc has not absorbed any of the

surrounding buffer. Thus, the FASTAB lacks a pH-stabilized agent, and there is no identifiable composition that satisfies the limitations of claim 14.

If the FASTAB is used in a hydrated form, the disc is already swollen with deionized water (see Levy, Example 1). In this form, the hydrated disc is unable to "take up or absorb liquid." In this way, the FASTAB does not satisfy the "absorbent matrix" element of claim 14, as defined in the specification.

If, however, the FASTAB is used partially hydrated, then some portion of the disc will be hydrated and the remainder will be dehydrated. For each hydrated portion of the disc, there is no "absorbent matrix" *per se*, as discussed above. And for the dehydrated portion, the pH-stabilized agent is lacking, also as discussed above. No matter what proportion of the partially hydrated disc is hydrated or dehydrated, each portion of the disc will fail to satisfy the limitations of claim 14 in at least one respect.

Rejected claims 16-18, which depend on base claim 14, do not read on the composition of Levy for the same reasons.

As to new claim 22, it should be noted that the "composition" in Levy is the incidental result of running a "correction" tube where the FASTAB is added to a buffer blank, forming a combined "composition." No "composition" is alleged by the "correction" tube and FASTAB separately. Assuming the stock phosphate buffer is 0.12M (column 14, lines 18-24), the final phosphate concentration in the "correction" tube is 13mM (column 13, lines 35-48). A concentration of 13mM phosphate buffer, pH 7.6, would not be considered a "sufficient quantity to prevent the formation of gas" by one skilled in the art in view of the teaching on page 6, lines 26-27 of the Specification.

Indeed, Example 1 of the specification teaches a composition that contains roughly 0.5M phosphate buffer. Claim 19 teaches compositions that vary from about 0.23M-5M phosphate, which can be almost 400 times the pH-stabilizing concentration as the "composition" in Levy. Because Levy only teaches the incidental combination of a FASTAB and the correction blank, Applicant submits that it does not teach a composition having "sufficient quantity" of pH-stabilizing agent "to prevent the formation of gas."

As to new claim 23, the combined Levy "composition" is not "substantially dry" excluding the humectant, but must be added to the buffer or contain deionized water, if in hydrated form (see Levy, Example 1, table).

Because Levy fails to teach each of the elements of the claims, Applicant respectfully requests that the Examiner remove this ground of rejection.

**Response to rejection of claims 1-13, 15, 19 and 21
under 35 U.S.C. § 103(a)**

The Examiner rejects claim 1-13, 15 and 21 for obviousness over Levy in view of U.S. Patent No. 4,999,163 to Lennon et al. ("Lennon"). Levy is applied as above, and Lennon is cited for its teaching of radioimmunoassay use and various structural features. Claim 19 is rejected for obviousness over Levy in view of Dean. Dean is cited for the relative proportion of disodium phosphate salts.

As discussed above, Levy fails to teach the limitation of an "absorbent matrix" or a "pH-stabilizing agent." Moreover, while Dean may discuss the equivalency of certain buffers, it does not suggest that sufficient quantity of pH-stabilizing agent should be used to prevent the formation of gas. In any case, one skilled in the art would not be motivated to use the teaching of FASTAB discs, which are used to selectively absorb or exclude antigens, in combination with the buffer present in a control sample, and extend this teaching with Dean to obtain a nonanalogous device for reducing the volatility of radioactive waste. Absent such motivation, extension of Levy in an unrelated direction would not be a matter of design choice.

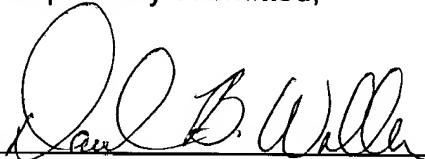
Because further citation of Lennon or Dean fails to remedy these deficiencies, Applicant respectfully requests that the Examiner remove this ground of rejection.

CONCLUSION

In view of the above, Applicant respectfully requests that the Examiner issue an allowance of the claims.

Respectfully submitted,

Date: 15 September 2003



David B. Waller
Registration No. 43,978

David B. Waller & Associates
5677 Oberlin Drive, Suite 214
San Diego, CA 92121

Telephone: (858) 457-2014
Facsimile: (858) 457-2308
E-mail: dwaller@cnmnetwork.com